

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of CEDGARD

Application No.: 09/465,667 Art Unit: 1651  
Filed: December 17, 1999 Examiner: Afremova  
Title: METHOD FOR THE PRODUCTION OF TABLETS BY PRESSING  
AND TABLETS PRODUCED BY THE METHOD

**RESUBMITTED BRIEF ON APPEAL**

Mail Stop Appeal Brief-Patents  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This is appellant's resubmitted brief to the Board of Patent Appeals and Interferences in support of the patentability of the claims in the above-identified application. This appeal stems from the Office Action mailed September 16, 2004, finally rejecting claims 11, 12, 14-21, 29 and 30 of the subject application. A Notice of Appeal from the final rejection was timely filed with the United States Patent and Trademark Office via facsimile on December 10, 2004. The requisite small entity fee set forth in 37 C.F.R. §1.17(c) was charged. Please charge as well any additional fees, such as extension fees pursuant to 37 CFR 1.136, required for or incurred as a result of this communication to Deposit Account No. 501249, referencing our docket number 74706.

Respectfully submitted,

November 22, 2006

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### **REAL PARTY IN INTEREST**

All rights to the subject application were assigned, via an unrecorded assignment, from the named inventor to Wasa Medicals AB, a company incorporated in Sweden. Wasa Medicals AB is the real party in interest to the above-identified patent application.

### **RELATED APPEALS AND INTERFERENCES**

There are no other appeals or interferences related to this application known to appellant, appellant's legal representative, or appellant's assignee and no decision in any other appeal or interference impacts the decision in the present appeal.

### **STATUS OF CLAIMS**

Claims 1- 10, 13 and 28 are cancelled.

Claims 22-27, 31 and 32 are allowed.

Claims 11, 12, 14-21, 29 and 30 stand finally rejected under 35 U.S.C. §103(a) and appeal is taken from the final rejection of these claims 11-12, 14-21, 29 and 30. A listing of all the claims is set forth in the attached Claims Appendix.

**STATUS OF AMENDMENTS FILED SUBSEQUENT TO  
FINAL REJECTION**

There were no amendments presented subsequent to the final rejection mailed September 16, 2004.

### **SUMMARY OF CLAIMED SUBJECT MATTER**

The present invention is directed to a method of producing tablets which include live bacteria. The method comprises mixing at least one strain of live bacteria with at least one fructose oligosaccharide and compressing the mixture to form a tablet having a friability of 0.1-1.0 while maintaining at least about 60% viability of the bacteria following the compression See inter alia page 2, lines 16-19 and page 5, lines 19-22 of the description. According to certain embodiments of the invention, the live bacteria may be lactic acid producing bacteria (see page 2, lines 25-27) and/or the fructose oligosaccharide may be inulin (see inter alia page 2, lines 29-33)

At page 4, lines 8-12 of the instant application, one advantage of the invention is summarized as follows: “The tablets according to the present invention have a lower hardness due to the lower punching pressure when the tablets are formed but an increased viability for the strain of bacteria, which makes every tablet more efficient than conventional tablets.” Further, on page 5, lines 24-28, a benefit of the present invention is described thus: “the new method results in an increased maintained viability after tablet punching of up to 200% compared with conventional tablet fillers. The increased yield results in an appreciably better economy and quality improvement of the above products.”

**GROUND OF REJECTION TO BE REVIEWED ON APPEAL**

Claims 11, 12, 14-21, 29 and 30 were rejected as being obvious and unpatentable under 35 U.S.C. §103(a) over the combination of US 4,396,631 taken with US 5,536,526, US 5,531,989, US 5,422,346, US 4,021,545 and US 4,806,368. This ground of rejection is presented for review. These claims are argued as a group.



## **ARGUMENT**

### 1. Rejection of claims 11,12, 14-21, 29 and 30 under 35 U.S.C. §103(a)

Parts of the record relied on:

US 4,396,631, US 5,536,526, US 5,531,989, US 5,422,346, US 4,021,545 and US 4,806,368 all cited in the Office Actions of 13 January 2004, 18 June 2004, 27 August 2004 and 16 September 2004.

Declaration by the inventor under 37 CFR 1.132 entered on 7 April 2004.

The rejection of claims 11, 12, 14-21, 29 and 30 under 35 U.S.C. §103(a) as being anticipated by US 4,396,631 taken with US 5,536,526, US 5,531,989, US 5,422,346, US 4,021,545 and US 4,806,368 is improper because the references are not properly combinable and further because even assuming, *arguendo*, the analogous references were combined, they fail to disclose each and every element of the invention as claimed.

#### (a)Deficiencies in the Individual References

##### **US 4,396,631**

The reference discloses mixing live bacteria with polysaccharides and providing the mixture, optionally, as a tablet, with the goal of long-term viability of the bacteria. This goal is achieved through the use of select pre-dried substances in addition to the bacteria and the basic compounding material.

US 4,396,631 fails to positively set forth limitations or recommendations for the friability of tablets produced with the described mixture. The absence of any disclosure related to friability can be a result of the fact that tableting is optional and not a critical step of the methods disclosed therein (see, *inter alia*, column 3, lines 28-32).

US 4,396,631 does not teach or even suggest the use of fructose oligosaccharide or inulin in the method for making hard tablets with live bacteria. Instead, it is the specific, disclosed pre-dried substances which, when present in particular amounts, provide the long-term viability that is the goal of the reference. For example, Example 1 uses 0.2 parts bacteria, 90.3 parts basic compounding material, 7 parts corn starch with 0.5% water content and 2.5 parts other (Column 4, lines 54-58).

Further, US 4,396,631 does not teach or even suggest a tablet with at least about 60% viability of bacteria following compression. There is a disclosure of  $2 \times 10^8$  bacteria after tableting (column 4, line 62). This measurement is used to compare the viability over time, as the number given for comparison is that of live bacteria after three months of storage, likely due to the fact that the reference is directed to solutions for long-term viability, not viability in the tableting process. Without a disclosure of the number of bacteria per gram prior to tableting, it is impossible to know if the reference teaches a method which, while still failing to disclose elements of the invention as noted above, does touch on the at least about 60% viability limitation presently claimed.

Thus, US 4,396,631 fails to teach or suggest friability limitations, fructose oligosaccharides or inulin in the mixture, and high viability after tableting, all of which form elements of the present invention.

#### **US 5,536,526**

The reference is directed to granulate compositions which can be used for direct compression tablets where sugar alternatives, particularly alternatives which do not induce dental caries, are preferred. US 5,536,526 does not teach or even suggest live bacteria in the tablets. Therefore, it further fails to teach or even suggest at least about 60% viability of bacteria following compression.

US 5,536,526 discloses friability in the range of 0-3 (column 4, line 7). However, there is no discussion of whether this friability range would be appropriate for tablets which have live bacteria and long-term viability, as is the goal of US 4,396,631.

#### **US 5,422,346**

The reference is directed to methods of pressing juice to form inulin tablets. US 5,422,346 does not teach or even suggest compressed tablets with a friability between 0.1 and 1.0. Hardness is discussed; however, as noted in US 5,536,526, hardness and friability are two separate considerations (see US 5,536,526, column 3, lines 52-53). Friability is not discussed in US 5,422,346.

US 5,422,346 does not teach or even suggest compressed tablets with live bacteria, therefore the reference also fails to teach bacterial viability of about at least 60% following compression. US 5,422,346 discusses bacteria, however, it is in the

context of detailing the relevance of maintaining healthy intestinal bacterial flora, one method of which is to consume the inulin tablets disclosed therein. There is no suggestion that inulin tablets would be useful in a compressed tablet with live bacteria.

#### **US 5,531,989**

The reference discloses dietary supplements comprising dietary fiber and immunoglobulin, live bacteria are optionally provided.

US 5,531,989 does not teach or even suggest forming tablets. Thus, the reference further fails to teach or even suggest compressed tablets with a friability between 0.1 and 1.0. The US 5,531,989 composition, instead, is provided as a liquid or as a powder intended to be reconstituted for administration in liquid form.

US 5,531,989 does disclose compositions containing bacteria, however, because the reference fails to teach or even suggest tableting it furthermore fails to teach that at least about 60% of the live bacteria are viable after tableting.

#### **US 4,021,545**

The reference discloses compounds which can be used to inhibit the mammalian complement system. The compounds may be mixed with inulin and formed into tablets.

US 4,021,545 fails to teach or even suggest compressed tablets with a friability between 0.1 and 1.0. Hard shell capsules are discussed; however, it is not clear from the disclosure whether the intention is a hard shell capsule filled with the composition or whether it is a capsule-shaped form with a hard shell. Regardless, as noted in US 5,536,526, hardness and friability are two separate considerations (see US 5,536,526, column 3, lines 52-53). Friability is not discussed in US 5,422,346.

US 4,021,545 fails to teach or even suggest compressed tablets with live bacteria, therefore the reference also fails to teach bacterial viability of about at least 60% following compression.

#### **US 4,806,368**

The reference is directed to dietary fiber tablets which contain live bacteria. US 4,806,368 does not teach or even suggest the use of fructose oligosaccharide or inulin in the method for making hard tablets with live bacteria.

Further, US 4,806,368 does not teach or even suggest compressed tablets with a friability between 0.1 and 1.0.

(b) Impropriety of the Combination of References

The references cannot properly be taken as a whole. The references which might be combinable, taken together, do not teach or even suggest the claimed invention. In the final rejection, US 4,396,631 is relied upon as a primary reference, and is combined with a series of unrelated references in a hindsight attempt to recreate the invention at the time of filing. This rejection is improper and should be withdrawn.

US 4,396,631 is directed to live-bacteria containing mixtures, optionally tablets, which have good long-term viability. It does not positively set forth limitations or recommendations for the friability of tablets produced with the described mixture. It does not teach or even suggest the use of fructose oligosaccharide or inulin in the method for making hard tablets with live bacteria. It does not teach or even suggest a tablet with at least about 60% viability of bacteria following compression.

US 4,806,368 also discloses tablets with bacteria but not inulin. In that regard, it might be combined with US 4,396,631 by a skilled worker, however, it does not remedy the significant deficiencies in the US 4,396,631 disclosure.

US 5,536,526 discloses tableting techniques related to friability. The compositions disclosed therein include neither inulin nor live bacteria. It is not proper to combine US 5,536,526 with US 4,806,368 as the former is not related to the unique technical problem of live bacteria in tableted form. Nothing in the US 5,536,526 disclosure would lead a skilled worker to expect that the methods taught therein would allow for the formulation of a live bacteria-comprising tablet with long-term viability. Thus, the combination of references is improper.

US 5,422,346 and US 4,021,545 are directed to inulin-containing tablets which do not contain live bacteria. A skilled worker attempting to formulate an improved composition for long-term viability of live bacteria-comprising compositions (as taught in US 4,396,631) would not look to the disclosures of US 5,422,346 and US 4,021,545. As with US 5,536,526, there is nothing in the disclosure of either 5,422,346 or US 4,021,545 that would lead a skilled worker to

expect that the compositions or methods taught therein would allow for the formulation of a live bacteria-comprising tablet with long-term viability.

Further, US 5,422,346 teaches away from combination with US 4,396,631 by teaching, as pointed out in the Office Action at page 3, fourth full paragraph, that the inulin tablets described therein do not require additional binding materials, such as starch (column 8, lines 41-44). It is the starch component of 4,396,631 that is essential for the long-term viability of the bacteria in the tablets, removal of which would defeat the purpose of the composition disclosed therein. Thus, there is no motivation in US 5,422,346 to modify US 4,396,631 in an attempt to render part of the claimed subject matter obvious.

US 5,531,989 discloses a composition of live bacteria and inulin, which composition is not tableted. If a skilled worker were following the non-tableted teachings of 4,396,631, they might possibly look to US 5,531,989 for guidance, however, for the purposes of rendering the present invention obvious US 5,531,989 is a completely irrelevant, non-analogous reference and should not be considered.

It is not only Appellant's view that the references are not properly combinable and, those which might be combined, do not suggest the claimed subject matter. Attention is drawn to the Declaration of Henning G. Kristensen under 37 C.F.R. §1.132 ("Kristensen Declaration"), filed April 7, 2004 in the instant case. Dr. Kristensen is a skilled worker in the relevant art as described in paragraph numbers 2-4 of the Kristensen Declaration.

In paragraph number 5, Dr. Kristensen declares: "a person having ordinary skill in the art of pharmaceutical formulation would not have combined the features of the cited patent references to arrive at the invention" and supports the statement with further remarks in paragraph 21: "there would not be any motivation or guidance apparent to a person of average skill in the art to combine the six references. Adachi [US 4,396,631] and Reddy [US 4,806,368] disclose tablets with bacteria but not inulin. Mitchell [US 5,422,346] and Nair [US 4,021,545] disclose tablets with inulin but not bacteria. Paul [US 5,531,989] discloses bacteria and inulin but not in a tablet, and Virtanen [US 5,536,526] discloses tablets but without inulin or bacteria."

Dr. Kristensen goes on to declare in paragraph 22: "[b]ased on the references available at the time of the invention, it was not known that the claimed method of producing tablets including live bacteria and supporting substance, *e.g.* inulin, where

the tablet has a friability of 0.1-1.0 and maintains at least about 60% viability of the bacteria following the tablet formation was possible. But the claimed method can be performed and results in a product with unexpected benefits, including high bacterial viability. From my knowledge and experience, I know that bacterial survival in conventional tablets is approximately 20%, so the about 60% viability of the claimed method is unexpected and remarkable.”

The appellant has established that the rejection of claims 11, 12, 14-21, 29 and 30 in the final action mailed September 16, 2004 is improper. In sum, the references are not properly combinable and, even if combined, they fail to teach each and every limitation of the claims as they currently stand.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of CEDGARD

Application No.: 09/465,667

Art Unit: 1651

Filed: December 17, 1999

Examiner: Afremova

Title: METHOD FOR THE PRODUCTION OF TABLETS BY PRESSING  
AND TABLETS PRODUCED BY THE METHOD

**CLAIMS APPENDIX**

The claims pending in the case are:

1-10 (cancelled)

11. A method of producing a tablet including live bacteria comprising the steps:

- a) mixing at least one strain of said live bacteria with at least one fructose oligosaccharide to form a mixture,
- b) compressing said mixture so as to form said tablet having a friability of between 0.1 and 1.0 while maintaining at least about 60% viability of said bacteria following the compression.

12. The method of claim 11 wherein said fructose oligosaccharide is present in an amount of about 40 – 99.5% by weight of said tablet.

13. (cancelled)

14. The method of claim 11 wherein said fructose oligosaccharide is inulin.

15. The method of claim 11 wherein said bacteria are lactic acid producing bacteria.

16. A method of producing a tablet including live bacteria comprising the steps:
  - a) mixing at least one strain of live lactic acid producing bacteria with at least one fructose oligosaccharide to form a mixture; and
  - b) compressing said mixture so as to form said tablet having a friability of between 0.1 – 1.0 while maintaining at least about 60% viability of said lactic acid-producing bacteria.
17. The method of claim 16 wherein said fructose oligosaccharide is inulin.
18. The method of claim 16 further comprising adding at least one pharmaceutically acceptable additive to said bacteria and said fructose oligosaccharide prior to said pressing step.
19. The method of claim 16 further comprising adding microcrystalline cellulose to said bacteria and said fructose oligosaccharides prior to said pressing step.
20. The method of claim 16 further comprising adding starch to said bacteria and said fructose oligosaccharide prior to said pressing step.
21. The method of claim 16 further comprising adding calcium diphosphate to said bacteria and said fructose oligosaccharide prior to said pressing step.
22. A method of producing a tablet including live bacteria comprising the steps:
  - a) mixing live bacteria *Str. Thermophilus*, *L. Bulgaricus*, *Bifidobacterium animalmis*, or *L. Plantaris* with inulin to produce a mixture; and
  - b) compressing said mixture so as to form said tablet having a friability of between 0.1 – 1.0 while maintaining at least about 60% viability of said bacteria.
23. The method of claim 22 further comprising adding at least one pharmaceutically acceptable additive to said live bacteria and said inulin.
24. The method of claim 22 further comprising adding calcium diphosphate to said live bacteria and said inulin.



25. The method of claim 22 further comprising adding microcrystalline cellulose to said live bacteria and said inulin.
26. The method of claim 22 further comprising adding starch to said live bacteria and said inulin.
27. A method of producing a tablet including live bacteria comprising the steps;
- a) mixing at least one live bacteria selected from the group consisting of *Str. Thermophilus*, *L. Bulgaricus*, *Bifidobacterium animalmis* and *L. Plantaris* with inulin and at least one additive selected from the group consisting of microcrystalline cellulose, calcium diphosphate and starch; and
  - b) compressing said mixture so as to form said tablet having a friability of between 0.1 – 1.0 and maintain at least about 60% viability of said *Str. Thermophilus*, *L. Bulgaricus*, *Bifidobacterium animalmis* and *L. Plantaris* bacterium.
28. (Cancelled)
29. The method of claim 11, wherein the friability of the tablet is between 0.3 and 0.5.
30. The method of claim 16, wherein the friability of the tablet is between 0.3 and 0.5.
31. The method of claim 22, wherein the friability of the tablet is between 0.3 and 0.5.
32. The method of claim 27, wherein the friability of the tablet is between 0.3 and 0.5.

## EVIDENCE APPENDIX

Declaration of Inventor under 37 CFR 1.132 entered on 7 April 2004:

### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of

Lennart CEDGARD

Application No.: 09/465,667

Art Unit: 1651

Filed: December 17, 1999

Examiner: Afremova, V.

Title: METHOD FOR THE PRODUCTION OF TABLETS BY PRESSING  
AND TABLETS PRODUCED BY THE METHOD

### DECLARATION UNDER 37 C.F.R. §1.132

Assistant Commissioner for Patents

Washington, D.C. 20231

Sir:

I, Henning G. Kristensen, hereby declare that:

1. I am a citizen of Denmark residing in Denmark.
2. My formal education includes attendance at the Royal Danish School of Pharmacy in Copenhagen, Denmark, where I received my Masters in Pharmacy in 1963. In 1968 I received my PhD from the Department of Pharmaceutics at the Royal Danish School of Pharmacy. I also received my Doctor of Pharmacy from the Royal Danish School of Pharmacy in 1981.
3. From 1968-1970, I was an Assistant Professor in the Department of Pharmaceutics at the Royal Danish School of Pharmacy. From 1970-1973, I was a Research Fellow and from 1973-1977 I was an Associate Professor in the same department. In 1978 I became a Full Professor of Pharmaceutics, and remain a Full Professor of Pharmaceutics at the Royal Danish School of Pharmacy today. Particular fields of research and teaching in which I specialize are the formulation, processing, and quality control of oral drug products, in particular solid dosage forms such as tablets and capsules. I possess the requisite knowledge related to the quality requirements of raw materials for the manufacture of drug products and the quality requirements of drug products.

4. Through a combination of education and experience I am a skilled worker in the field of pharmaceuticals and pharmaceutical formulation. I have reviewed and understand U. S. Patent Application No. 09/465,667 ("the '667 application"). I am also familiar with the Office Action dated January 13, 2004.

5. Based on my background and experience in the field of pharmaceuticals and pharmaceutical formulation, it is my opinion that at the time of the invention of the subject matter disclosed in the '667 application, a person having ordinary skill in the art of pharmaceutical formulation would not have combined the features of the cited patent references to arrive at the invention set forth in each of the claims of the '667 application, for reasons set forth more clearly below.

6. Attached and labelled as Kristensen Declaration Exhibit 1 is a true copy of the '667 application as filed with the United States Patent and Trademark Office.

7. Attached and labelled as Kristensen Declaration Exhibit 2 is a true copy of the claims presently on file in the '667 application

8. Attached and labelled as Kristensen Declaration Exhibit 3 is a true copy of the Office Action dated January 13, 2004, containing the above-mentioned rejection of the claims of Exhibit 2.

9. Attached and labelled as Kristensen Declaration Exhibit 4 is a true copy of U.S. Patent No. 4,396,631 Adachi et al.

10. Attached and labelled as Kristensen Declaration Exhibit 5 is a true copy of U.S. Patent No. 5,536,526 to Virtanen et al.

11. Attached and labelled as Kristensen Declaration Exhibit 6 is a true copy of U.S. Patent No. 5,531,989 to Paul.

12. Attached and labelled as Kristensen Declaration Exhibit 7 is a true copy of U.S. Patent No. 5,422,346 to Mitchell et al.

13. Attached and labelled as Kristensen Declaration Exhibit 8 is a true copy of U.S. Patent No. 4,021,545 to Nair et al.

14. Attached and labelled as Kristensen Declaration Exhibit 9 is a true copy of U.S. Patent No. 4,806,368 to Reddy.

15. Hereafter the patents mentioned in paragraphs 9 to 14 will be referred to by the first inventor name, or by their Exhibit number. The other exhibits will simply be referred to by their Exhibit number.

16. The Office Action of January 15, 2004, rejects all pending claims, Claims 11, 12, 14-27 and 29-32, based on Adachi in view of Virtanen, Paul, Mitchell, Nair, and Reddy. Adachi discloses mixing live bacteria with polysaccharides in a tablet. Virtanen discloses tableting techniques related to friability. Paul discloses non-tablet compositions comprising inulin and bacteria. Mitchell discloses non-bacteria containing tablets of inulin. Nair discloses producing non-bacteria containing tablets with inulin and other additives such as starch or calcium diphosphate. Reddy discloses bacterial tablets.

17. The invention of the '667 application, as disclosed and claimed is a method of producing tablets including live bacteria. The method comprises mixing at least one strain of live bacteria with at least one supporting substance such as fructose oligosaccharide and compressing the mixture to form a tablet having a friability of 0.1-1.0, maintaining at least about 60% viability of the bacteria following the compression. According to certain embodiments of the invention, the live bacteria may be mixed with inulin.

18. At page 4, lines 8-12 of Exhibit 1, one advantage of the invention claimed in the '667 application is summarized as follows: "The tablets according to the present invention have a lower hardness due to the lower punching pressure when the tablets are formed but an increased viability for the strain of bacteria, which makes every tablet more efficient than conventional tablets." Further, on page 5, lines 24-28, a benefit of the present invention is described thus: "the new

method results in an increased maintained viability after tablet punching of up to 200% compared with conventional tablet fillers. The increased yield results in an appreciably better economy and quality improvement of the above products.”

19. I agree with the statements on page 4 of Exhibit 3 that Adachi fails to positively set forth friability of tablets, and that Adachi fails to disclose the use of fructose oligosaccharide or inulin in the method for making hard tablets with live bacteria. It is correct that Adachi does not disclose all elements of the invention of the ‘667 application. I do not agree with the apparent conclusion on page 3 that the Adachi disclosure of  $2 \times 10^8$  bacteria after tableting inherently discloses a tablet with at least about 60% viability of bacteria following compression.

I agree with the statements on page 4 of Exhibit 3 that Paul is silent about both hardness and friability. This is because the Paul composition is not a tablet.

20. Based on my background and experience in the field of pharmaceutical formulation it is my opinion that a person of average skill in the art of pharmaceutical formulation would recognize the disclosure and claims of the ‘667 application to be directed to a novel method of tablet production. Further, this person of average skill would recognize that neither Adachi, Virtanen, Paul, Mitchell, Nair nor Reddy disclose the novel method because there are significant differences in the disclosures and benefits of each respective invention.

21. In addition to the recognition that shortcomings exist when considering the references singly, there would not be any motivation or guidance apparent to a person of average skill in the art to combine the six references. Adachi and Reddy disclose tablets with bacteria but not inulin. Mitchell and Nair disclose tablets with inulin but not bacteria. Paul discloses bacteria and inulin but not in a tablet, and Virtanen discloses tablets but without inulin or bacteria.

22. Therefore, I believe a person of average skill in the art of pharmaceutical formulation would recognize the disclosure and claims of the ‘667 application are patentably distinct from the disclosures of Adachi, Virtanen, Paul, Mitchell, Nair and Reddy. Based on the references available at the time of the invention, it was not known that the claimed method of producing tablets including

live bacteria and supporting substance, *e.g.* inulin, where the tablet has a friability of 0.1-1.0 and maintains at least about 60% viability of the bacteria following the tablet formation was possible. But the claimed method can be performed and results in a product with unexpected benefits, including high bacterial viability. From my knowledge and experience, I know that bacterial survival in conventional tablets is approximately 20%, so the about 60% viability of the claimed method is unexpected and remarkable.

23. All statements made herein of my own knowledge are true and all statements made on information and belief are believed to be true; and further these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

March 28, 2004  
Date

Henning G. Kristensen  
Henning G. Kristensen